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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,859	09/06/2001	Bronwyn Jean Battersby	21415-0005	4713
26633 7590 11/16/2007 HELLER EHRMAN LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER EPPERSON, JON D	
			ART UNIT	PAPER NUMBER
			1639	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/856,859	Applicant(s) BATTERSBY ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-29, 63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-29, 63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. The Response filed August 31, 2007 is acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 15-29 were pending. Applicants added claims 30-31 and amended claims 15, 17, 22, and 24. No claims were canceled. Therefore, claims 15-29, 63, and 64 are pending and examined on the merits.

Priority

4. Applicants' claim for foreign priority is not perfected because the foreign priority document fails to provide adequate support for the currently claimed invention under 35 U.S.C. 112, first paragraph (e.g., see MPEP § 706.02(b), "The filing date of the [foreign] priority document is not perfected unless ... the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph"; see also *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds).

Here, Australian Patent PP7372 (referred to herein as '372) filed 11/30/1998 fails to

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provide adequate support under 35 U.S.C. § 112 for the currently claimed invention.

Specifically, '372 fails to provide support for the limitation wherein "the population of detectably distinct carriers constitutes at least about 70% of the plurality of carriers" as disclosed in independent claim 15. In addition, '372 fails to provide support for the "quantifiable" attributes. The '372 application also fails to disclose a carriers that comprise all the attributes that define a code before commencing synthesis and further fail to disclose carriers that are covalently coupled to a synthon suitable for use in combinatorial synthesis. The '372 application also fails to disclose attributes of a respective carrier that are comprised within or internally of the carrier as set forth in claim 16. The '372 application also fails to disclose the genus of electromagnetic radiation related attributes as set forth in claim 17. The '372 application also fails to provide support for the light transmittance and electrical impedance as set forth in claim 18. In addition, '372 fails to provide support for light emitting and light transmitting attributes set forth in claim 19. If applicant believes this to be in error, applicant must disclose where in the specification support for these limitations can be found (i.e., page and line number). Therefore the filing date of the instant application is deemed to be the filing date of PCT/AU99/01065, *November 30, 1999*.

Withdrawn Objections/Rejections

5. The objections to claims 17 and 22 are withdrawn in view of Applicants' amendments thereto. The 35 U.S.C. § 112, second paragraph rejections denoted "A-C" are withdrawn in view of Applicants' amendments to claims 15, 21, and 24. The "new matter" rejection under 35 U.S.C. § 112, first paragraph is withdrawn in view of Applicants' amendments to claim 15. The

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Lee rejection under 35 U.S.C. § 102 is withdrawn in view of Applicants' amendments to claim 15.

New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 15-29, 63, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 15**, the phrase “wherein said plurality of carriers comprises a plurality of synthons” is vague and indefinite. For example, it is not clear why this phrases is set forth when line 3 of the same claim already states that each carrier is covalently coupled to a synthon? Thus, the statement would appear to be redundant. Applicants are requested to clarify and/or correct. Therefore, claim 15 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in

(1) an application for patent, published under section 122(b), by another filed in the United States before the

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invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 15-29, 63, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Natan et al. (U.S. Patent No. 7,225,082 B1) (Priority to **October 1, 1999** via 60/157,326).

For *claim 15*, Natan et al. disclose a plurality of carriers on which a plurality of different compounds can be synthesized (e.g., see abstract; see also figure 1; see also column 3, lines 40-53, “Also included within the present invention is an assembly or collection of particles comprising a plurality of types of particles, wherein each particle is from 20 nm to 50 pm in length and is comprised of a plurality of segments, and wherein the types of particles are differentiable”). Natan et al. also disclose a population of detectably distinct carriers (e.g., see column 3, lines 40-5) wherein wherein each carrier is covalently coupled to a synthon suitable for use in combinatorial synthesis (e.g., see column 9, paragraph 3, “In many embodiments of the present invention, one or more segments of the particle, the ends of the particle, or the entire particle may be functionalized. By functionalization, or attachment of a functional unit, it is meant that some species or material is covalently or noncovalently attached to the surface of the particle. Examples of functionalization include the attachment, often via a linker, to an antibody or antibody fragment, to an oligonucleotide or a to a detectable tag; see also column 10, paragraph 1; see also column 24, paragraph 2, “One of the well known methods are used to affixe the 45-mer to the surface : one involves the use of thiol-labeled DNA, and another uses standard EDC coupling to amine terminated DNA”; see also column 25, second to last

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paragraph, “oligonucleotides will be attached chemically (i.e., by covalently adsorption of thiols”; see also column 27, paragraph 1; see especially column 27, paragraph 2, “nanorods are synthesized possessing SAMs terminated with carboxyl functionality by reacting the rods with o-carboxy alkanethiols. The carboxyl functionality is then activated to an anhydride for further reaction with a wide variety of amines with diverse functional groups ... [including] dextran lactones ... Subsequent cleavage of the lactone with amines carrying diverse functional groups yields a library of hydroxy amides of dextran coated nanoparticles ... By appropriately choosing and designing structurally different amine reactant cocktails for derivatization, there is an opportunity to create a vast library of surfaces. These combinatorially-derivatized nanoparticles present surfaces with varying avidity for binding to the wide variety of molecules present in a biological sample”; see also column 18, paragraph 2; see also column 26, paragraph 2). Please note that any of the covalently attached molecules set forth above including the SAMs, nucleic acids of the oligonucleotide, amino acids of the antibody, dextran lactones, amine carrying diverse functional groups, etc. could be considered as “synthons suitable for use in combinatorial synthesis” because all have been used to make libraries. In addition, Natan et al. disclose carriers having a code which distinctively identifies a respective carrier before during and after said synthesis from other carriers (e.g., see abstract; see also figure 1; see also column 3, lines 40-57; see also column 4, last paragraph describing these segmented nanoparticles as “bar codes”). In addition, Natan et al. disclose that the carriers are characterized by at least two detectable and or quantifiable attributes integrally associated with the carrier wherein individual carriers comprise all the attributes that define a corresponding code before commencing synthesis of a respective compound thereon wherein one of said attributes is not shape or surface

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deformation of the carrier (e.g., see column 3, lines 40-49, “Also included within the present invention is an assembly or collection of particles comprising a plurality of types of particles, wherein each particle is from 20 nm to 50 pm in length and is comprised of a plurality of segments, and wherein the types of particles are differentiable. In the preferred embodiments, the particle types are differentiable based on differences in the length, width or shape of the particles and/or the number, composition, length or pattern of said segments. In other embodiments, the particles are differentiable based on the nature of their functionalization.”; see also column 9, paragraph 2 disclosing half and half magnetic/optical properties). Please note that while one of the attributes may not be shape or surface deformation of the carrier that does not mean that the other one cannot be. Thus, the current claims read on nanobars that are distinctively labeled by shape and length or shape and segment composition, etc. Finally, Natan et al. disclose a population of detectably distinct carriers that constitutes at least about 70% of the plurality of carriers (e.g., see column 8, last paragraph, “The present invention includes assemblies or collections of nanobar codes made up of a plurality of particles that are differentiable from each other [i.e., 100% are different]”; see also column 9, “In many applications, the functionalization is different and specific to the specific flavor of nanoparticle [i.e., 100% are different].”; see also column 3, lines 40-56; see especially, 8, last full paragraph, “In certain embodiments, the members of the assembly are identical, while in other embodiments, the assembly is comprised of a plurality of different types of particles.”)

For **claim 16**, Natan et al. disclose the plurality of carriers of claim 15 wherein at least one of said attributes of a respective carrier is comprised within or internally of the carrier (e.g., see column 3; lines 40-49 disclosing composition of segments; see also lines 54-56 disclosing the

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inclusion of dyes within the segments; see also column 16, second to last paragraph; see also column 8 describing the segments as being “coated”).

For **claims 17-19**, Natan et al. disclose the plurality of carriers of claim 15 wherein at least one of said attributes of a respective carrier is an electromagnetic radiation related attribute wherein the electromagnetic radiation related attributed is selected from the group consisting of fluorescence emission, luminescence, phosphorescence, infrared radiation, electromagnetic scattering including light and x-ray scattering, light transmittance, light absorbance, and electrical impedance and said radiation-related attributed includes, light emitting, light transmitting or light absorbing (e.g., see column 13, lines 45 and 46, “Thus, light scattering can identify the overall length of a nanobar code”; see also column 20, lines 31-46, “The ability to make complex bar codes is of no consequence without an effective method for reading the bar codes. Fortunately ... bar codes ... can be visualized using conventional light microscopy”; see also column 21; last paragraph disclosing the use of fluorescence microscopy in addition to light microscopy; see also column 25, line 40 disclosing the emission of light; see also column 15, paragraph 1, “a variety of detection mechanisms can be used , including but not limited to optical detection mechanisms (absorbance, fluorescence Raman, hyperRaman, Rayleigh scattering hyperRayleigh scattering, CARS, sum frequency generation ... [etc].”).

For **claim 20**, Natan et al. disclose the plurality of carriers of claim 15 wherein a respective carrier has at least three detectable and or quantifiable attributes integrally associated therewith (e.g., see column 5, last full paragraph wherein length, width, shape, segment composition are disclosed; see also column 3, lines 40-49).

For **claim 21**, Natan et al. disclose the plurality of carriers of claim 17 wherein the

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electromagnetic radiation related attribute of a respective carrier is fluorescence and said carrier comprises a fluorescent dye (e.g., see figure 4; see also column 6, paragraph 1; see also column 15, paragraph 1; see also column 21, paragraphs 1 and 2; see also column 22, paragraphs 1-4; see also column 24, last paragraph; see especially column 29, lines 2 and 3).

For **claim 22**, Natan et al. disclose the plurality of carriers of claim 15 wherein each carrier is a colloidal particle (e.g., see title; see also column 13, lines 35-37, “In addition, it is also possible to create colloidal rods containing three or more types of segments and with three or more orthogonal chemistries”; see also column 14, paragraphs 2 and 3; see also column 22, last paragraph).

For **claim 23**, Natan et al. disclose the plurality of carriers of claim 15 wherein the carriers have different shapes selected from the group consisting of spheres, cubes, rectangular, prisms, pyramids, cones, ovoids, sheets, or cylinders (e.g., see figure 1; see also column 6, lines 25 and 26, “In short, cylindrically-shaped nanoparticles offer surface properties that are useful for bioassay construction”).

For **claim 24**, Natan et al. disclose the plurality of carriers of claim 15 wherein the carriers have different forms selected from the group consisting of pellet, disc, capillary, hollow, fiber, needle, pin, and chip (e.g., see figure 1; see also column 18, line 5; see also column 45, line 10; see also column 2, paragraph 2).

For **claim 25**, Natan et al. disclose the plurality of carriers of claim 15 wherein the carriers have different sizes (e.g., see column 3, lines 49-49; see also column 13, lines 47-48; see especially column 16, paragraph 1).

For **claim 26**, Natan et al. disclose the plurality of carriers of claim 22 wherein the

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colloidal particle is polymeric or ceramic particle (e.g., see column 3, paragraph 3, "The segments of the particles of the present invention may be comprised of polymeric materials"; see also column 9, line 59 disclosing the use of ceramic materials).

For **claim 27**, Natan et al. disclose the plurality of carriers of claim 26 wherein the ceramic particle is a silica particle (e.g., see column 3, line 30 wherein glass is disclosed).

For **claim 28**, Natan et al. disclose the plurality of carriers of claim 26 wherein the carriers comprise ceramic particles with different diameters selected from about 0.01 to about 150 μm (e.g., see column 7, lines 9-15, "The width, or diameter, of the particles of the invention is within the range of 5nm-50 μm ").

For **claim 29**, Natan et al. disclose the plurality of carriers of claim 15 wherein a respective carrier comprises functionalities selected from the group consisting of NH_2 , COOH , SOH , SSH , and sulfate (e.g., see column 10, paragraph 1 disclosing acids, amines, thiols, etc.).

For **claim 63 and 64**, Natan et al. disclose the plurality of carriers according to claims 15 or 21 wherein said synthons are coupled to said carriers by a linker (e.g., see column 9, lines 49-40-47, "By functionalization, or attachment of a functional unit, it is meant that some species or material is covalently ... attached to the surface of the particle. Examples of functionalization include the attachment, often via a linker, to an antibody or antibody fragment, to an oligonucleotide").

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/
Primary Examiner, AU 1639